

REMARKS

Prior to this Amendment, claims 1-12, 16-34, 36-42 and 60-73 were pending in this application. By this Amendment, Applicants have amended claims 1, 29, 60 and 72 without prejudice or disclaimer of the subject matter recited therein.

Applicants do not acquiesce in the Examiner's rejections, but instead have elected to make the above-mentioned amendments in an effort to expedite prosecution of this application leading to issuance of a patent. Reconsideration of the application as amended above and in view of the following remarks is earnestly solicited.

Claims Rejection under 35 U.S.C. § 103 - Duvillier in view of Kienzle, III

The Examiner has rejected Claims 1-12, 16-34, 36-42 and 60-73 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,749,876 to Duvillier et al. ("Duvillier") in view of U.S. Patent No. 6,478,802 to Kienzle, III, et al. ("Kienzle"). As will be explained below, Applicants respectfully submit that the above combination of references do not support the Examiner's rejection of the present claims as amended under 35 U.S.C. § 103(a).

Legal Standards

A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. Section 103(a); see Graham v. John Deere Co., 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). "The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness." In re Dembiczkak, 50 USPQ2d 1614, 1616 (Fed. Cir. 1999).

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined), must teach or suggest all the claim limitations. M.P.E.P. § 2143.

Analysis

Independent claims 1, 29, 60 and 72 have each been amended to include a limitation that the second cutting guide is spaced apart from the first cutting guide by a first distance and the third cutting guide is spaced apart from the second cutting guide by a second distance. Moreover, the limitation also requires that the spaces between the cutting guides (as defined by the first and second distances) are independently adjustable with respect to one another. This limitation is in direct contrast to the teachings of Duvillier, which teaches a cutting block device in which respective cutting blocks move in concert with one another and specifically in a proportionate manner. For instance, and referring to column 7, lines 40-65, device 12 comprises means 61 for proportionally adjusting the spacing between blocks (21, 24 and 30). To accomplish this, means 61 comprises two lateral flanges 62 in the form of a plate, wherein the flanges are mounted in rotation about pins 37 on either side of block 24 and into slots 64. Slots 64 are shaped in an arc like configuration and disposed symmetrically in relation to the axis that passes through pins 37. The plate also includes notches 65, which are designed to cooperate by catching two spindles on the upper slots (i.e., spindles 38) and two spindles on the lower slots (i.e., spindles 36). Regarding the orientation of the upper and lower slots, these slots are inclined in relation to the horizontal so that when blocks 21 and 24 are moved apart from one another, complementary movement between blocks 24 and 30 is achieved in a proportional manner. In other words, when flanges 62 are pivoted forward and backward, the blocks are displaced vertically between two positions – i.e., one in which the three blocks are spaced apart to a maximum and one in which the blocks are pressed up against one another. As such, the spacing between blocks 21 and 24 and blocks 24 and 30 cannot be adjusted independently of one another. This is in stark contrast to the present invention as defined by independent claims 1, 29, 60 and 72. More particularly, these claims specifically require that the second cutting guide be spaced apart from the first cutting guide by a first distance and the third cutting guide be spaced apart from the second cutting guide by a second distance. Moreover, the spaces between the cutting guides (as defined by the first and second distances) are independently adjustable with respect to one another.

The above-described deficiencies of Duvillier are also not resolved by the teachings of Kienzle, which describes a computer assisted surgery system for accurately positioning a drill bit into a body part. Not only does Kienzle specifically fail to teach independently adjustable cutting blocks, in fact, its teachings has absolutely nothing to do with resection/cutting blocks, let

alone techniques for placing resection/cutting blocks during a surgical navigation (image guidance) procedure. Even assuming, *arguendo*, that Duvillier could be relied on as the Examiner asserts, Applicants assert that there is absolutely no motivation to combine its teachings with that of Kienzle along the lines of the present invention. More particularly, many surgical procedures, including bone resections, are viewed as complicated processes because they are sometimes performed invasively. When a procedure is performed invasively, the risk that the patient may suffer from associated surgical complications is inherently increased. For instance, many conventional knee procedures involve the insertion of an IM rod into the bone marrow canal in the center of either the femur or tibia to assist in properly aligning the knee with the hip joint. However, because of the invasive application of such IM rods, patients are put at an increased risk of developing fat embolism (i.e., IM rods are capable of forcing body fat into a patient's blood stream). If this happens, the fat deposit may become lodged in the patient's heart or brain and cause the patient to suffer from heart failure, dementia, stroke or even infection. In addition to causing surgical complications, the use of invasive procedures also routinely slows the patient's recovery time.

As those of skill in the surgical navigation art would clearly understand and appreciate, unlike the teachings of Duvillier, the present invention is specifically directed to minimally invasive techniques. In particular, the present invention allows a surgeon to place a guide pin into a patient's bone by surgically navigating the pin to a targeted location, and then in turn, placing a cutting block over the pin to thereby perform a bone resection. Because the cutting block is surgically navigated into place, the use of referencing guides (e.g., "IM rods") and/or other such invasive instruments is not required, and in fact, would likely be discouraged.

As mentioned above, Duvillier is directed to a conventional (i.e., non-image guided surgical procedure), which requires the use of femoral intramedullary rods (see reference numeral 28) to perform its bone resection techniques. As Duvillier is directed to non-image guided procedures and has absolutely nothing to do with image guidance, Applicants believe that Duvillier is irrelevant to the present invention, and essentially can be considered non-analogous art. Accordingly, a skilled artisan guided by its teachings would not be inclined to formulate the image guided systems of the present invention. Moreover, an individual of ordinary skill in the surgical navigation art would not be motivated to look to the art of non-image guidance (such as taught by Duvillier) to formulate the surgical navigation resection procedures as claimed.

For an Examiner to properly rely on a reference under 35 U.S.C. § 103, the reference must be analogous prior art. *See M.P.E.P. § 2141.01(a).* “In order to rely on a reference as a basis for rejection of an applicant’s invention, the reference must either be in the field of applicant’s endeavor or, if not, then reasonably pertinent to the particular problem with which the inventor was concerned.” *In re Oetiker*, 977 F.3d 1443, 1446 (Fed. Cir. 1992). “A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor’s endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his problem.” *In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992). “Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempt to solve. If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference . . .” Id.

The purpose of the Duvillier reference is to invasively resect a bone with conventional non-image guided methods using intramedullary rods. Applicants’ invention, in stark contrast, is directed to solving the problem of improving bone resection accuracy by incorporating surgical navigation (image guided) techniques into the resection process. One of ordinary skill in the art would not be motivated to solve this problem by looking to Duvillier’s conventional and invasive resection procedures. Therefore, the Examiner’s reliance on Duvillier in combination with Kienzle is fundamentally flawed and is insufficient to support an obviousness rejection under 35 U.S.C. § 103(a). *See In re Fine*, 1837 F.2d 1071, 1073, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

Not only is there no requisite motivation for combining Duvillier and Kienzle along the lines of the invention to reach the claimed subject matter, there is also no teaching by either reference (whether viewed alone or in combination) of a second cutting guide spaced apart from the first guide by a first distance and a third cutting guide spaced apart from the second cutting guide by a second distance, and particularly wherein the spaces between the cutting guides (as defined by the first and second distances) are independently adjustable with respect to one another.

As explained above, both 35 U.S.C. § 103(a) and M.P.E.P. § 2143 require that when combining one or more references along the lines of an invention, the combined teachings must teach or suggest all of the claim limitations to properly support an obviousness rejection (emphasis added). Here, however, neither Duvillier nor Kienzle (whether viewed alone or in

combination) teach all of the limitations contained within independent claims 1, 29, 60 and 72. As such, one skilled in the relevant art would be unable to formulate the presently claimed invention from their combined teachings. Therefore, Applicants submit that claims 1, 29, 60 and 72 are nonobvious over and patently distinguishable from Duvillier in view of Kienzle, whereby the rejection under 35 U.S.C. § 103 has been overcome. Reconsideration is respectfully requested.

Dependent Claims 2-12, 16-28, 30-34, 36-42 and 61-71

Claims 2-12, 16-28, 30-34, 36-42 and 61-71 each depend from one of independent claims 1, 29, 60, 72 and 73. Since claims 1, 29, 60, 72 and 73 are believed to be allowable for the above discussed reasons, claims 2-12, 16-28, 30-34, 36-42 and 61-71 are also believed to be allowable. Removal of the rejection and allowance of claims 2-12, 16-28, 30-34, 36-42 and 61-71 is respectfully requested. If the Examiner should disagree with the Applicants' arguments, the Examiner is asked to kindly point out with particularity where these claimed limitations are expressly disclosed within the teachings of Duvillier in view of Kienzle.

Final Remarks

Applicants respectfully submit that the claims as presented are now in condition for allowance. Such allowance is respectfully requested.

If necessary, Applicants request that this Amendment be considered a request for an extension of time for a time appropriate for the response to be timely filed. Applicants request that any required fees for filing this Amendment be charged to the account of Bose McKinney & Evans LLP, Deposit Account Number 02-3223.

Respectfully submitted,

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